K011204

MAY - 8 2001

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
90 Icon Street
Foothill Ranch, California 92610
Phone: (949) 580-1555
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The device includes modifications to the EEG-1100A currently marketed per 510(k) # K992742, including the addition of new optional configurations and new accessories.

The device classification is unchanged. The device is classified by the Neurology Panel under 21 CFR Part 882.1400 "Electroencephalograph" per GWQ. Common names for the device include Electroencephalograph (EEG) and Polysomnograph (PSG).

The device as modified has the same intended use and indications for use as the existing marketed device and uses the same fundamental scientific technology. The device is intended to record, measure and display the physiological data required for EEG and sleep studies (Polysomnography or PSG). These data, may be used by the clinician in Sleep Disorders, Epilepsies and other disorders as an aid in diagnosis. This device is intended for use by medical personnel and will be available for use within a medical facility or outside of a medical facility under direct supervision of a medical professional.

The device does not directly contact patients. New accessories that contact patients such as the EEG electrodes are made from the same component materials as similar legally marketed accessories. Therefore, good laboratory practice studies were not required per 21 CFR part 58.

The EEG-1100A device is not sterile.

The device was developed in accordance with design controls and operation of the device was appropriately verified and validated using the same test methods as with the existing device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2001

Ms. Bonnie Bishop
Regulatory Affairs Manager
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, California 92610

Re: K011204
Trade/Device Name: Nihon Kohden EEG-1100A Series and Accessories
Regulation Number: 882.1400
Regulatory Class: II
Product Code: GWQ
Dated: April 18, 2001
Received: April 19, 2001

Dear Ms. Bishop:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

F. Indications for Use Statement

510(k) Number (if known): K011204

Device Name: EEG-1100A including EEG-9100A and Junction Box Option Configurations

Indications for Use:

The device has the same indications as the existing EEG-1100 per K992742.

The device is intended to record, measure and display cerebral and extracerebral activity for EEG and Sleep Studies. These data, may be used by the clinician in Sleep Disorders, Epilepsies and other related disorders as an aid in diagnosis.

The device is intended for use by medical personnel in any location within a medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under direct supervision of a medical professional. The device will be available on all patient populations (including adults and children) as determined by the trained professional.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011204